



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*C. Jurek
(PIB/FOD)*

JUN 28 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: FAP#6H5505. Chlorpyrifos for Use in Food Handling Establishments. EPA Reg. Nos. 62719-74 (Dursban® ME Insecticide), 62719-88 (Empire® 20 Microencapsulated Insecticide).
Amendment of March 3, 1990. Evaluation of Residue Data.
DEB No. 6583. MRID Nos. 414341-00, -01.

FROM: Michael T. Flood, Ph.D., Acting Section Head
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THROUGH: Richard D. Schmitt, Ph.D., Chief
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TO: Dennis Edwards, PM #12
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Introduction

In the present submission DowElanco (formerly Dow Chemical Company) has responded to deficiencies outlined in DEB's previous memoranda (M.Kovacs, memos of 2/5/88, 10/19/88). The submission includes a cover letter, dated 3/13/90, residue data and proposed labeling for Dursban® ME Insecticide and Empire® 20 Microencapsulated Insecticide.

Summary of Deficiencies Remaining to Be Resolved

- ° The petitioner must identify the matrix (meal) into which chlorpyrifos was spiked for the storage stability study.
- ° The petitioner should submit a revised Section B in which uses of Dursban® ME Insecticide and Empire® 20 Microencapsulated Insecticide are permitted in food service establishments but are prohibited in food manufacturing and/or food processing plants.
- ° The petitioner should propose a food additive tolerance of 0.1 ppm.

Conclusions and Recommendations (pertaining to this memo only)

- 1a. Residue data have been submitted which show that continuous low levels of chlorpyrifos are not expected from the proposed use in food service establishments. However because measurable levels in food have been found, the petitioner should propose a food additive tolerance of 0.1 ppm for residues of chlorpyrifos in food commodities exposed to the insecticide during treatment of food service establishments.
- 1b. Even though chlorpyrifos residues in food were occasionally observed as a result of the proposed use, anticipated residues for chronic dietary exposure analysis -- as opposed to tolerances -- in food commodities can be properly set at the limit of detection -- 0.005 ppm.
2. The submitted storage stability study indicates that chlorpyrifos is stable in a meal up to 45 weeks. However, the petitioner must identify the meal into which chlorpyrifos was spiked.
3. Proposed labels for both pesticide formulations do not distinguish between food service establishments (where use would be permitted) and food manufacturing or food processing plants (where use would not be permitted). The petitioner should submit a revised Section B in which Dursban® ME Insecticide and Empire® 20 Microencapsulated Insecticide are permitted in food service establishments but are prohibited in food manufacturing and/or food processing plants.

Detailed Considerations

This memorandum lists deficiencies noted in DEB's 2/5/88 and 10/19/89 memos, DowElanco's response and DEB's comments.

DEB Deficiency #1 (Deficiency #4a from our 2/5/88 memo)

Need for food item residue data to reflect Section B/proposed label use.

DowElanco Response

The company has submitted residue data in the following report:

"Determination of Chlorpyrifos Residues in Food Resulting from Treatment of Food Service Establishments with Dursban ME Insecticide," P.A. Nugent, 3/7/90, Project Identification GH-C 2292R. (MRID # 414341-01)

These residue data were collected in accordance with the protocol reviewed by DEB (M. Kovacs, memo of 10/19/88).

Dursban® ME Insecticide was applied at 0.5% at the Dow 2030 cafeteria and the restaurant at the Midland Country Club. The treatments were applied over three intervals. Applications were made to food and non-food areas at each site and were carried out at the times which they would normally occur in commercial practice -- between 6:00 and 7:00 A.M. Samples for analysis were taken from foods that were available at the time of treatment and were collected where they would normally be received by the customer. Each meal was replicated three times and was typical of food choices available that day. A list of food items collected and homogenized for each sampling time is given in Appendices C and D of the submission. The food service establishments treated were the Dow 2030 cafeteria and the restaurant at the Midland Country Club.

On day 0, three samples of food exposed at various stages of preparation were collected during application. Additionally, three replicates of complete meals from three consecutive serving periods, breakfast, lunch and dinner, were sampled on day 0 and again on days 7 and 13. After two weeks a second application was made and samples were collected according to the same schedule. A third and final application was made after two more weeks and samples collected again. After a meal was collected, the entire meal was put into one polyethylene bag and immediately taken to the sample preparation area at DowElanco in Midland, MI. The entire meal was homogenized and stored frozen until analysis at Fort Wayne, Indiana.

Samples were analyzed using a method very similar to those described earlier (see M. Kovacs, memo of 3/3/87). Chlorpyrifos is extracted from food with acetone and the sample filtered and brought to volume with acetone. A portion is evaporated and hexane is added with sodium sulfate, a drying agent. The hexane solution is then partitioned with acetonitrile, and the acetonitrile solution evaporated to dryness. The sample is then brought up in hexane, purified by silica gel chromatography and evaporated to dryness. The sample is brought up in 2.0 mL of hexane and the resulting solution analyzed for parent chlorpyrifos using gas chromatography with flame photometric detection.

Percent recoveries from food fortified at 0.01, 0.02, 0.04, 0.06 and 0.08 ppm varied from 30-110%. The low value occurred at

the 0.01 ppm fortification level [$73 \pm 21\%$ ($n=11$)]. Overall recoveries averaged $81 \pm 6\%$ ($n=44$). Despite the low value, recoveries are acceptable.

At the Dow 2030 Cafeteria, 76 of 90 samples showed non detectable residues of chlorpyrifos (<0.005 ppm); 5 samples showed residues greater than 0.01 ppm; and two samples showed residues of 0.06 and 0.07 ppm (corrected for recovery).

At the Midland Country Club, 90 of 90 samples showed non detectable residues of chlorpyrifos.

DEB Comment

In spite of two values higher than 0.05 ppm, the data indicate that chlorpyrifos residues should not be present in food for consumption on a continuous basis. Nevertheless, since food with chlorpyrifos residues resulting from treatment of food service establishments is a definite possibility, the petitioner should propose a tolerance for chlorpyrifos in food commodities resulting from the proposed use. On the basis of submitted data, we consider a food additive tolerance of 0.1 ppm to be adequate.

Even though residues in food were occasionally observed, anticipated residues for chronic dietary exposure analysis -- as opposed to tolerances -- in food commodities can be properly set at the limit of detection -- 0.005 ppm.

DEB Deficiency #2 (Deficiency #4b from our 2/5/88 memo)

Need for additional residue data reflecting the proposed Section B/labeling and, if needed, proposed food additive tolerances to cover expected residues on various food items exposed by the proposed use.

DowElanco Response

The submitted residue data [discussed above] are responsive to this deficiency.

DEB Comment

The residue data are responsive to this deficiency. Deficiency #2 is resolved.

DEB Deficiency #3 (Deficiency #1 from our 10/19/88 memo)

The submitted protocol as applicable to food service establishments only (i.e., proposed testing of cafeteria and restaurant) is acceptable to DEB provided the petitioner provides the appropriate storage stability data. This can be done by fortifying an

additional control meal at each cafeteria and restaurant test location with chlorpyrifos at levels approximating the anticipated food additive tolerance level, and then store the samples in a frozen condition until analysis at the termination of the study.

DowElanco Response

Storage stability data have been submitted with the residue data. A 300 g meal sample was spiked at 1.0 ppm and was analyzed at 0 days and 2,4,8 and 45 weeks. No significant degradation was observed during this period.

DEB Comment

Submitted data show that chlorpyrifos is stable over a 45 week period. However it is necessary that the company identify the matrix (meal) into which chlorpyrifos was spiked. Deficiency #3 remains.

DEB Deficiency #4 (Deficiency #2 from our 10/19/88 memo)

The submitted protocol as applicable to food manufacturing and processing establishments is not acceptable to DEB.....

DowElanco Response

The company proposes to register microencapsulated chlorpyrifos for use in food service establishments only. Therefore, tests were limited to food service establishments.

Proposed Section B labeling has been included for Dursban® ME Insecticide and Empire® Microencapsulated Insecticide:

Dursban® ME Insecticide.

The following statement has been deleted from the previous label:

Do Not Use This Product In Food Areas Of Food Handling Establishments Or Other Areas Where Food Is Prepared Or Processed.

The underlined phrase in the following sentence has been deleted:

Applications may also be made within nonfood areas of industrial, institutional, and commercial buildings, including hospitals, stores, manufacturing plants, and warehouses.

A paragraph insert has been added. Applications within food

service establishments such as restaurants and cafeterias are limited to spot and/or crack and crevice treatment. For spot treatments, an individual spot should not exceed 2 square feet. Repeat treatment as needed but not more than once every 14 days.

Empire® 20 Microencapsulated Insecticide.

There is no statement on the label prohibiting use in food areas of food handling establishments or other areas where food is prepared or processed.

The phrase "nonfood areas of" has been deleted from the paragraph analogous to that for the Dursban® ME label.

A paragraph insert has been added that is similar to the insert for the Dursban® ME label.

DEB Comment

If the two pesticide formulations are to be registered for use in food service establishments only, additional protocols and resulting residue data are unnecessary. However, the revised labels do not prohibit use in food manufacturing or processing plants. The petitioner must submit a revised Section B which permits use in food service establishments but not in food manufacturing or processing plants. Deficiency #4 remains.

Other Considerations

Dursban® ME Insecticide and Empire® 20 Insecticide are identical microencapsulated chlorpyrifos formulations except for the amount of active ingredient. The former contains 11.7% chlorpyrifos and the latter contains 20.0% chlorpyrifos. Dursban® ME is produced by diluting Empire® 20 Insecticide with water. When diluted with water to produce operational mixtures for use in pest control treatments, the products are applied at the same active ingredient rates. Submitted data are therefore applicable to both formulations.

cc: RF, SF, Circu. Reviewer(MikeFlood), C.Furlow(PIB/FOD).
H7509C:DEB:Reviewer(MTF):CM#2:Rm800A:557-4362:typist(mtf):6/21/90.
RDI:BranchSeniorScientist:RALoranger:6/20/90.